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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY-DOCKET NO. | CONFIRMATION NO. |
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| 09/837,797 | 04/17/2001 | Henry C. Lin | (18810-81652) | 9913 |

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01/09/2003

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 01/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/837,797

Applicant(s)

LIN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25October2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicants' Response to Restriction, received 25 October 2002, paper#6, is acknowledged.

Applicants elect, without traverse, Invention I, claims 1-28, drawn to method of treatment of SIBO, classified in class 424, subclass 9.1.

Applicants Response to Species Election is acknowledged. Applicants elect, without traverse, species A, nutrient deprivation.

2. Claims 21-45 have been canceled, as requested, without prejudice.

3. Claims 1-20, drawn to nutrient deprivation are pending and under consideration.

Priority

4. The parent applications have been reviewed and are not enabled for treatment of SIBO by deprivation bacterial populations of nutrients or single nutrient. Therefore the effective filing date for claims 1-20 which are drawn to said treatment is the same as the instant application, i.e., 4/17/2001.

Drawings

5. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Information Disclosure Statement

6. Applicants' Transmittal of and Information Disclosure Statement, received 5 March 2002, paper#4, is acknowledged. However, there appears to be problems with the IDS, detailed in the following:

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The submitted Form PTO-1449 indicates 18 pages. However, pages 17 and 18 are merely copies of pages 15 and 16.

Page 1, paragraph 2, states that copies of references Nos. 137-161 and the patents on page 15 have been submitted with the IDS form. However, no such references have been found in the application.

Page 1, paragraph 2, states that patents on pages 1-4 and 17 as well as references listed as 1-136 and 162-177 have not been submitted because the art was previously cited by the Examiner and/or the applicants in connection with U.S. Ser. Nos. Listed in the priority statement. The examiner has checked the prior applications and could only find references 162-176 in the parent applications. The current examiner has made copies of the U.S. Patents listed on the IDS. The examiner regrets the inconvenience to the applicants, but if the rest of the nonpatent references listed as ref. Nos. 1-162 and 177 are to be considered, the examiner requests that copies of these references be submitted.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of SIBO in irritable bowel syndrome patients with a predigested nutritional formula VIVONEX® alone, does not reasonably provide enablement for treatment of SIBO or other SIBO caused conditions by deprivation of all/some nutrients or single nutrient nor of combination therapies with enzymes, absorption alterations, or any other therapies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - method of treating SIBO or a SIBO caused condition in a human subject, said method comprising: 1) detecting SIBO, and if SIBO is present, 2) depriving

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the bacterial population of nutrients sufficiently to inhibit the growth of said bacterial and thereby partially eradicating SIBO in said subject.

The state of the prior art indicates that SIBO is detectable in a variety of afflictions of mammals. Therapy includes surgery, diet changes (in dogs and cats), and/or antibiotic therapy to reduce the level of SIBO. Nutritional requirements of bacteria found in SIBO is well-known. However, the ability to alter the bacterial levels in SIBO through diet alone by depriving the bacteria of an essential nutrient or nutrients is not well known.

The amount of direction or guidance present - The instant specification provides only one example of the claimed nutrient deprivation method, i.e., example 11, which uses a commercially available composition, VIVONEX®, which comprises many predigested nutrients. All of the patients involved in the study are diagnosed with irritable bowel syndrome. No other patients with other diagnosis are included. There are no examples of single nutrient deprivation being successful for treating SIBO, nor is there guidance for determining which single nutrient would be successful. The example does not provide evidence that any conditions of the patients other than reduction in SIBO have been altered.

The quantity of experimentation necessary to fulfill the scope of the instant claims constitutes merely an invitation to experiment, without a reasonable expectation of success in determining what single nutrient treats SIBO.

Conclusion

10. No claims are allowed.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

January 8, 2003